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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

09/837,800

DANIEL A. JAPUNTICH ET AL.

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		AARC	JN J. LEWIS	,	3/61	
	The MAILING DATE of this communication appears	on the cover	sheet with t	he corres	pondence addres	s
Period f	for Reply					
THE N - Extens mailing	ORTENED STATUTORY PERIOD FOR REPLY IS SET MAILING DATE OF THIS COMMUNICATION. ions of time may be available under the provisions of 37 CFR 1.136 (a).	In no event, how	ever, may a rep	bly be timely	filed after SIX (6) MON	
- If NO p - Failure - Any re	period for reply specified above is less than thirty (30) days, a reply with period for reply is specified above, the maximum statutory period will app to reply within the set or extended period for reply will, by statute, caus ply received by the Office later than three months after the mailing date patent term adjustment. See 37 CFR 1.704(b).	ply and will expire se the application	SIX (6) MONTH to become ABA	iS from the r NDONED (35	nailing date of this con 5 U.S.C. § 133).	/. ımunication.
Status	,					
1) 💢	Responsive to communication(s) filed on 11/06/20	002 (AMEND)	MENT)			
2a) 🗌	This action is FINAL . 2b) 🔀 This ac	tion is non-fir	nal.		•	:
3) 🗆	Since this application is in condition for allowance closed in accordance with the practice under Ex pa					merits is
Disposi	tion of Claims					
4) 💢	Claim(s) 33-37, 50-53, and 55-85			is	are pending in	the application.
4	a) Of the above, claim(s)			is	are withdrawn	from consideratio
5) 🗆	Claim(s)				is/are allowe	ed.
6) 💢	Claim(s) 33-37, 50-53, and 55-85				is/are reject	ed.
7) 🗆	Claim(s)				is/are object	red to.
8) 🗆	Claims		are subje	ect to res	striction and/or e	lection requirement
Applica	tion Papers					
9) 🗆	The specification is objected to by the Examiner.					
10)	The drawing(s) filed on is/a	real acc	epted or b	objec o	ted to by the Ex	aminer.
	Applicant may not request that any objection to the					
11)	The proposed drawing correction filed on		_ is: a\[approved	d b disapprov	ed by the Examine
	If approved, corrected drawings are required in reply	to this Office	action.		•	
12)	The oath or declaration is objected to by the Exam	niner.				
`	under 35 U.S.C. §§ 119 and 120					
13)∟	Acknowledgement is made of a claim for foreign p	oriority under	35 U.S.C.	§ 119(a)-(d) or (f).	
	☐ All b)☐ Some* c)☐ None of:					
	1. Certified copies of the priority documents ha					
	2. ☐ Certified copies of the priority documents ha					·
	 Copies of the certified copies of the priority of application from the International Bure ee the attached detailed Office action for a list of the attached detailed of the action for a list of the attached detailed of the action for a list of the attached detailed of the action for a list of the attached detailed of the action for a list of the action for	eau (PCT Rul	e 17.2(a)).		i this National S	age
	Acknowledgement is made of a claim for domestic)(e).	
	The translation of the foreign language provision					
15)	Acknowledgement is made of a claim for domestic	c priority und	er 35 U.S.	C. §§ 12	0 and/or 121.	
Attachm	ent(s)					
1) 🔲 No	otice of References Cited (PTO-892)	4) Interviev	v Summary (PT	О-413) Раре	r No(s).	
	otice of Draftsperson's Patent Drawing Review (PTO-948)	_	f Informal Pater	nt Application	n (PTO-152)	
3) 💢 In	formation Disclosure Statement(s) (PTO-1449) Paper No(s). 07	6) Other:				

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DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine 1. grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 33-37,50-53,55-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-38,40-74,78-81 of copending Application No. 08/240,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each co-pending application are drawn to a filtering face mask adapted to fit over the nose and mouth of a wearer and having an

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exhalation valve which has a flap retaining stationary surface and a second free portion which lifts away from its seat during user exhalation. Further, the valve flap has a curved profile in a cross sectional view in a closed state. While certain features (e.g.the flexible flap being secured to the valve seat non-centrally relative to the orifice at the flap retaining surface; the flap retaining surface and the seal surface being nonaligned and positioned relative to each other to allow for a cross-sectional curvature of at least the one free portion of the flexible flap when viewed from the side in a closed position, the nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowing for the one free portion of the flexible flap to be pressed against the seal surface when a wearer of the mask is neither inhaling nor exhaling and to allow for the one free portion of the flexible flap to be lifted from the seal surface during an exhalation.) are omitted from base claim 33 of the instant application whereas base claim 78 of application ('877) includes these features, the mere omission of an element and its function is an obvious expedient if the remaining elements perform the same function as before. In re Karlson, 136 USPQ 184 (CCPA 1963). Also note Ex parte Rainu, 168 USPQ 375 (Bd. App. 1969). Omission of a reference element whose function is not needed would have been obvious to one of ordinary skill in the art...

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

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- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 33-37,76-78,50-53,55-63,65-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of McKim ('168).

As to claim 33, Simpson et al. disclose a filtering face mask that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer, the mask body comprising a filtration layer (page 1, lines 108-113) through which inhaled air may pass before being inhaled by a wearer of the face mask; and an exhalation valve (fig. 2) that is attached to the mask body, the exhalation valve allowing air exhaled by a wearer to pass from an interior of the mask body to its exterior without having to pass through the filtration layer, the exhalation valve comprising: a valve seat that comprises: a seal surface (page 2, lines 37-50 and #19); and an orifice (16) that is circumscribed by the seal surface; and a single flexible flap (15) that has only one stationary portion (page 2, lines 46-50) and only one free portion and a circumferential edge, the circumferential edge having a first segment that is associated with the one stationary portion of the flap so as to remain at rest during an exhalation and having a second segment that is associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second segment of the circumferential edge also being located below the first segment when the filtering face mask is worn on a person (fig. 1).

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The difference between Simpson et al. and claim 33 is the flexible flap being mounted to the valve seat such that the one free portion of the flap exhibits a curvature when viewed from the side in the closed position and is pressed towards the seal surface in an abutting relationship with it, under any orientation of the exhalation valve, when a fluid is not passing through the orifice.

McKim teaches a flexible flap being mounted to the valve seat such that the one free portion (opposite the fixed portion #14a as illustrated in figs. 1 and 3) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for the purpose of seating quickly, effectively and without float or bounce after each opening (col.1, lines 64-72).

It would have been obvious to modify the exhalation valve of Simpson et al. to be mounted to the valve seat such that the one free portion (opposite the fixed portion #14a as illustrated in figs. 1 and 3) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for because it would have provided for seating quickly, effectively and without float or bounce after each opening as taught by McKim.

As to claim 34, the flexible flap of Simpson et al. as modified by McKim is not wholly circular when view from the front (see fig.2 of McKim).

As to claim 35, Simpson et al. (figs. 1 and 2) illustrate the second segment of the circumferential edge of the flexible flap having a circular curvature that corresponds to a circularly shaped seal surface disposed beneath the second segment of the flap's circumferential edge.

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As to claims 36 and 37, the valve seat of Simpson et al. as modified by McKim (#15 and #28 of fig.3) illustrates a planar flap retaining surface, the flexible flap being mounted to the flap-

retaining surface.

As to claim 76, the flap retaining surface includes two securement points both disposed outside

a region encompassed by the orifice (e.g. see #17 of McKim).

As to claims 77 and 78, the curvature in the flexible flap (14) of McKim (fig. 1) extends from a

point where the flap os mounted to the valve seat to a second point where the free portion of the

flexible flap makes contact with the seal surface and the curvature does not have an inflection

point.

As to claim 50, Simpson et al. (fig.2) discloses the valve seat including a flange portion that

defines a mounting surface for the valve seat, which surface extends 360 degrees around the valve

seat an its base and enables the valve seat to be secured to the mask body.

As to claims 51-53, McKim (fig. 1) teaches the flexible flap assuming a curved profile, when in

its closed state, the extends in from where the flexible flap contacts a retaining surface on the

valve seat to where the second portion of the flexible flap contacts the seal surface of the valve

body portion. Further, the flap retaining surface is oriented transversely to and adjacent the orifice

in Simpson et al. and in McKim (fig.2).

As to claim 55, the flexible flap of Simpson et al. is mounted to the valve seat in cantilever

fashion.

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As to claim 56, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including a relatively light weight plastic. Inasmuch as Simpson et al. (page 2, lines 37-65) disclose the valve flap being made from plastic and/or rubber material, it would have been obvious to make the valve seat from any well known material which would achieve known or expected results including a plastic and/or rubber material because the use of a valve seat of the same material as the valve flap would have provided for more effective physically cooperation.

As to claim 57, Simpson et al. disclose the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 39-42). The seal (figs.2 and 3) of Simpson et al. are illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed of being made from plastic and since known physical characteristices of plastics include flexibility and resiliency, the flap (15) of Simpson et al. being made from plastic is fully capable of providing the recited function of "...capable of allowing the flap to display a bias towards the seal surface.".

As to claim 58, the bias of the valve flap of Simpson et al. as modified by McKim is generated by the mounting of the flap to the valve seat as illustrated by McKim.

As to claims 59 and 60, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal. Further, it stands to reason

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that one oridinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade. The flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claim 61, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 62, Fig. 2 of Simpson et al. illustrate the flexible flap (15) to be longer in the direction extending from the first segment of the circumferential edge to the second segment.

As to claim 63, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

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As to claim 65, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claims 66 and 67, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 68, the exhalation valve of Simpson et al. (fig. 1) is positioned on the mask body substantially opposite to a wearer's mouth.

As to claim 69, the flap retaining surfaces of Simpson et al. and McKim are located around the periphery of the orifice; therefore, the flap retaining surfaces are not disposed substantially in the path of the exhale flow stream.

As to claim 70, Simpson et al. (fig.2) disclose a plurality of openings (16) seperated by cross members, the openings being disposed within the orifice and beneath a point where the flexible flap (12) is mounted to the valve seat when viewing the filtering face mask from the front in an upright position (fig. 1).

As to claim 71, Simpson et al. as discussed above with respect to claim 70 discloses exhaled passing primarily through a plrality of openings (16).

As to claim 72, the valve seat of Simpson et al. (fig. 2) includes a flap retaining surface (page 2, lines 46-50) that is located outside the region defined by the plurality of openings (16).

5. Claims 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-37,76-78,50-53,55-63,65-72 above, and further in view of Shindel ('277)

The difference between Simpson et al. as modified by McKim and claim 73 is a valve cover, the valve cover having an opening that allows exhaled air to pass therethrough and also having a surface that holds the flexible flap against the flap-retaining surface on the valve seat.

Shindel (col.2, lines 59-66) teaches a valve cover (7), the valve cover having an opening that allows exhaled air to pass therethrough and also having a surface (14) that holds the flexible flap against the flap-retaining surface on the valve seat. Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices. Additionally, the cover would have provided a means for directing fluid which passes through the orifice as well as protecting the valve flap against debris.

It would have been obvious further modify the valve of Simpson et al. to add a valve cover because it would have provided for simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices and because it would have provided a means for directing exhaled gas away from a wearer's face and provided a means for protecting the valve flap against debris as taught by Shindel.

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As to claims 74 and 75, the flexible flap of Simpson et al. as further modified by Shindel is mounted the valve seat by mechanical clamping (fig.2 of Shindel) and the flap-retaining surface (5) of Shindel is disposed on one side of the seal surface (fig. 2 of Shindel).

Claims 79,80-82 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6. Simpson et al. in view of McKim as applied to claims 33-37,76-78,50-53,55-63,65-72 above, and further in view of Warbasse ('706).

The difference between Simpson et al. as modified by McKim and claim 79 is a valve cover that has an opening that permits exhaled air to pass therethrough, the valve cover also having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first segment of the circumferential edge towards the second segment of the edge.

Warbasse (fig.2) teaches a valve cover (11) that has an opening that permits exhaled air to pass therethrough, the valve cover also having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first segment of the circumferential edge towards the second segment of the edge.

It would have been obvious to further modify the mask of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap, controlling the movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse.

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As to claim 64, the flexible flap and valve cover of Simpson et al. as further modified by Warbasse are positioned on the valve seat such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person (fig.2 of Warbasse).

As to claim 80, the opening in the valve cover of Simpson et al. as further modified by Warbasse (fig.2) is positioned directly in the path of fluid flow approximately parallel to the path traced the by second segment of the circumferential edge during opening and closing of the free portion of the flexible flap (12).

As to claims 81 and 82, the valve seat's orifice (16) of Simpson et al. (fig.2) is circular and has one or more cross members disposed within the orifice.

7. Claims 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33-37,76-78,50-53,55-63,65-72 above, and further in view of Braun ('362).

The difference between Simpson et al. as modified by McKim and claim 83 are cross members which are slightly recessed beneath the seal surface when viewed from a side elevation.

Braun teaches cross members (19,20) disposed within the orifice and which are slightly recessed beneath the seal surface (18) for the purpose of increasing the sealing force (col.4, lines 36-41). The cross members would assist in preventing the flexible flap from being drawn into the orifice during an inhalation.

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It would have been obvious to further modify the position of the cross members of Simpson et al. to slightly recess them beneath the seal surface because it would have increased the sealing force of the valve as taught by Braun.

As to claim 84, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface.

As to claim 85, Braun teaches a seal ridge (18) which extends upwardly of a peripheral mounting flange for the purpose of increasing the sealing force.

Response to Arguments

- 8. Applicant's arguments with respect to claims 33-37,50-53,55-85 have been considered but are most in view of the new ground(s) of rejection.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

January 26, 2003

Aaron J. Lewis
Primary Examiner